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## UNITED STATES DEPARTMENT OF COMMERCE

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	APPLICATION NO.	FILING DATE	FIRST	NAMED INVENTOR		ATTORNEY DOCKET NO.	
09/	430,034 10,	/29/99 B	DVA	F	62	:56	
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			QM12/0130	,			
DENNIS P CLARKE					MANTIS MERCADER.E		
MILES & STOCKBRIDGE					ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

01/30/01

	Application No.	Applicant(s)						
Office Action Surrange	09/430,034	BOVA ET AL.						
Office Action Summary	Examiner	Art Unit						
	Eleni Mantis Mercader	3737						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.								
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> </ul>								
1) Responsive to communication(s) filed on <u>29 October 1999</u> .								
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Thi	2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This action is non-final.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Disposition of Claims  4) Claim(s) 1-23 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-23 is/are rejected.  7) Claim(s) is/are objected to.  8) Claims are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are objected to by the Examiner.  11) The proposed drawing correction filed on is: a) approved b) disapproved.								
12) The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. § 119	mainaite under 25 II O.O. C.4404	o) (d)						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:  1. received.  2. received in Application No. (Series Code / Serial Number)  3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.								
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).								
Attachment(s)								
14) Notice of References Cited (PTO-892)  15) Notice of Draftsperson's Patent Drawing Review (PTO-948)  16) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)							

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 9, 15-16, 19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kormos et al. '890.

Regarding claims 9, 15-16, 19 and 23 Kormos et al.'890 teach a system of medical procedures, the system comprising:

a locator attachable to a patient, having at least 3 fiducial markers thereon (col. 3, lines 31-44);

a medical device for performing diagnostic imaging or a therapeutic medical procedure on a patient (col. 3, line 46-59);

a sensing subsystem for sensing the positions of the fiducial markers when the patient is in a position for performing the medical procedure using the medical device (col. 4, lines 4-27);

and

wherein the locator has a registration portion for registration with a portion of a patient's body, the locator being mechanically free such that the patient is positionable without applying

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forces to the locator during the patient positioning, and wherein the locator is molded to fit external features of a specific patient (col. 3, lines 3-34).

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-8, 10-14, and 17-18, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kormos et al.'890 in view of McLaurin'117.

Kormos et al.'890 teach the use of thermoplastic mesh material with markers affixed on this material, placed over the area of interest for imaging guided surgery. Kormos et al.'890 do not teach the use of this material for repeated use in imaging and therapy, and wherein the area of interest is the head/face. In the same field of endeavor, McLaurin'117 teaches the use of this material for repeated use in imaging and therapy, and wherein the area of interest is the head/face (see Abstract).

It would have been obvious to one skilled in the art at the time that the invention was made to have used the thermoplastic mesh material as taught by Kormos et al.'890 in subsequent procedures or at a later time as taught by McLaurin'117 in order to facilitate subsequent visits for treatment (see McLaurin'117 col. 2, lines 25-51). Furthermore, it would have been obvious to

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one skilled in the art at the time that the invention was made, to have used this thermoplastic material over the area of interest as demonstrated by both Kormos et al.'890 and McLaurin'117.

The prior art made of record and not relied upon is considered pertinent to applicant's 5. disclosure.

Cosman et al.'541 teaches a head band for frameless stereotactic registration.

6. Any inquiry concerning this communication should be directed to Eleni Mantis Mercader at telephone number (703) 308-0899. The examiner's supervisor, Mr. Marvin Lateef, can be reached on (703) 308-3256.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858. The fax phone number for this Group is (703) 308-0758.

> Marvin M. Lateef Supervisory Patent Examiner Group 3700

January 26, 2001.